



Serial No. 09/787,327
Docket No. PU3514USW

Clean Copy of The Claims

Claim 1 (Amended) A combination comprising (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof and a second therapeutic agent, bis(pivaloyloxymethyl)(9-[(R)-2-(phosphonomethoxy)ethyl]adenine or a pharmaceutically acceptable derivative thereof wherein (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-pyrimidin-2-one and the second therapeutic agent are present in the range 40:1 to 1:1 by weight.

Claim 2. A combination according to claim 1 wherein the ratio is in the range 25:1 to 15:1 by weight of active ingredients.

Claim 3 (Cancelled).

Claim 4 (Amended) A pharmaceutical formulation comprising a combination according to claim 1 in association with one or more pharmaceutically acceptable carriers therefor.

Claim 5 (Amended) A pharmaceutical formulation for use in the treatment of HBV comprising (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof and a second therapeutic agent selected from (9-[(R)-2-(phosphonomethoxy)ethyl]adenine or a pharmaceutically acceptable derivative thereof, and bis(pivaloyloxymethyl)(9-[(R)-2-(phosphonomethoxy)ethyl]adenine or a pharmaceutically acceptable derivative thereof wherein (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-pyrimidin-2-one and the second therapeutic agent are present in the range 40:1 to 1:1 by weight.

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Claim 6 (Amended) A formulation according to claim 4 in unit dosage form.

Claim 7 (Amended) A formulation according to claim 4 suitable for oral administration.

Claim 8 (Amended) A formulation according to claim 5 comprising between 25 to 150 mg of lamivudine and 5 to 60 mg adefovir dipivoxil.

Claim 9 A formulation according to claim 8 comprising 100 mg of lamivudine and 10 mg adefovir dipivoxil.

Claim 10. (Amended) A method for the treatment of a mammal with an HBV infection comprising administration of a therapeutically effective amount of a combination comprising (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof and a second therapeutic agent selected from (9-[(R)-2-(phosphonomethoxy)ethyl]adenine or a pharmaceutically acceptable derivative thereof, and bis(pivaloyloxymethyl)(9-[(R)-2-(phosphonomethoxy)ethyl]adenine or a pharmaceutically acceptable derivative thereof.

Claim 11 (cancelled)

Claim 12 (Amended) A method according to claim 10 wherein the combination is administered simultaneously.

Claim 13 (Amended) A method according to claim 10 wherein the combination is administered sequentially.

Claim 14 (Amended) A method according to claim 10 wherein the combination is administered as a single combined formulation.

Claim 15 (Amended) A method as claimed in claim 10 for the treatment of an HBV infection resistant to nucleoside and/or non-nucleoside inhibitors of the replication of the hepatitis B virus.

Claims 16-21 (Cancelled).

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Claim 22 (Amended) A patient pack comprising of at least one active ingredient selected from (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-pyrimidin-

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2-one, and bis(pivaloyloxymethyl)(9-[2-(phosphonomethoxy)ethyl]adenine and an information insert containing directions on the use of both active ingredients together in combination.

Claim 23. (New) A method according to claim 10 wherein the mammal is a human.

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